H. R. 4733

To establish and fund an Opioids and STOP Pain Initiative to expand, intensify, and coordinate fundamental, translational, and clinical research of the National Institutes of Health with respect to opioid abuse, the understanding of pain, and the discovery and development of safer and more effective treatments and preventive interventions for pain.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 21, 2017

Mr. WELCH (for himself and Mr. MCKINLEY) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Budget, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To establish and fund an Opioids and STOP Pain Initiative to expand, intensify, and coordinate fundamental, translational, and clinical research of the National Institutes of Health with respect to opioid abuse, the understanding of pain, and the discovery and development of safer and more effective treatments and preventive interventions for pain.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Opioids and STOP Pain Initiative Act".

SEC. 2. ESTABLISHMENT.

There is established an Opioids and STOP Pain Initiative, to be administered by the Director of the National Institutes of Health, in coordination with other agencies, as appropriate, which shall include efforts to support research on the following:

- (1) Section 108 of the Comprehensive Addiction and Recovery Act of 2016 (<u>42 U.S.C.</u> <u>284q–1</u>), known as the STOP Pain Act, which directs the National Institutes of Health to intensify and coordinate fundamental, translational, and clinical research with respect to—
 - (A) the understanding of pain;
 - (B) the discovery and development of therapies for chronic pain; and
 - (C) the development of alternatives to opioids for effective pain treatments.
 - (2) Developing improved options and evidence for medication-assisted treatment.
- (3) Developing improved options and evidence for opioid overdose reversal treatments.
 - (4) The Federal Pain Research Strategy, including research that focuses on—
 - (A) novel drugs, non-addictive, and non-pharmacological treatments for pain;
 - (B) screening tools and outcome measure for assessments across the continuum of pain;
 - (C) national registries, datasets, and research networks;
 - (D) effective models of care delivery for pain management; and
 - (E) precision medicine methodology to prevent and treat pain.
- (5) The components of the Department of Health and Human Services five-point strategy to address the opioid crisis that states: "Providing support for cutting edge research on pain and addiction".
 - (6) The pain therapy screening program established under section 4.
- (7) Other elements that the Secretary of Health and Human Services may designate, in consultation with the Director of the National Institutes of Health.

SEC. 3. FUNDING FOR THE OPIOIDS AND STOP PAIN INITIATIVE.

(a) IN GENERAL.—There is authorized to be appropriated, and there is appropriated, \$5,000,000,000, to be used during the 5-fiscal-year period beginning in the fiscal year in which such funds are appropriated, to the National Institutes of Health Innovation Account to be used to administer the Opioids and STOP Pain Initiative established under section 2.

(b) EMERGENCY SPENDING.—

- (1) IN GENERAL.—Amounts appropriated under subsection (a) are designated as an emergency requirement pursuant to section 4(g) of the Statutory Pay-As-You-Go Act of 2010 (2 U.S.C. 933(g)).
- (2) DESIGNATION IN THE SENATE.—In the Senate, amounts appropriated under subsection (a) are designated as an emergency requirement pursuant to section 403(a) of S. Con. Res. 13 (111th Congress), the concurrent resolution on the budget for fiscal year 2010.

SEC. 4. PAIN THERAPY SCREENING PROGRAM.

- (a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall carry out through the National Institutes of Health a program to be known as the "Pain Therapy Screening Program" that focuses on the development of pain therapeutics.
- (b) GRANTS.—The Secretary shall award grants under the program under subsection (a) to eligible public and private nonprofit entities to support the development of new pre-clinical models for pain disorders, and the application of these models in drug, device, or other therapy screening.
- (c) MODEL.—The program under this section shall be modeled after the Epilepsy Therapy Screening Program carried out by the National Institute of Neurological Disorders and Stroke.
- (d) FEES.—The Secretary of Health and Human Services may assess reasonable fees on private pharmaceutical or medical device industry entities that utilize the program under this section to screen proprietary molecular compounds and devices. Such fees shall be paid to the Foundation for the National Institutes of Health and transferred to the NIH Innovation Account to be used for the Opioids and STOP Pain Initiative established under section 2.
- (e) FUNDING.—The Director of the National Institutes of Health shall determine the amount, and allocate, funds from the amount appropriated under section 3, to carry out this section.

SEC. 5. FUNDING PROVISIONS.

- (a) SUPPLEMENT NOT SUPPLANT.—Amounts appropriated in this Act (including the amendments made by this Act) shall be used to supplement, not supplant, current funding for pain and opioid research at the National Institutes of Health.
- (b) ACCEPTANCE OF DONATIONS.—Notwithstanding section 1342 of title 31, United States Code, the Secretary of Health and Human Services may accept donations (including from the pharmaceutical and medical device industries) to be used to assist in carrying out programs and activities under this Act (and the amendments made by this Act). Such donations shall be paid to the Foundation for the National Institutes of Health and transferred to the NIH Innovation Account to be used for the Opioids and STOP Pain Initiative established under section 2.
- (c) INCLUSION OF CONTRIBUTION AMOUNTS IN BASIC RESEARCH FOR PURPOSES OF RESEARCH CREDIT.—
 - (1) IN GENERAL.—Paragraph (6) of section 41(e) of the Internal Revenue Code of 1986 is amended by adding at the end the following new subparagraph:
 - "(E) OPIOIDS AND STOP PAIN INITIATIVE.—The National Institutes of Health, if the payment is made in support of the Opioids and STOP Pain Initiative, as established by the Opioids and STOP Pain Initiative Act"...".
 - (2) EFFECTIVE DATE.—The amendments made by this subsection shall apply to taxable years beginning after the date of the enactment of this Act.

SEC. 6. AUTHORITY.

Notwithstanding any other provision of the law, the Director of the National Institutes of Health may use funds available under section 3 to enter into transactions (other than contracts, cooperative agreements, or grants) to carry out research identified pursuant to the Opioids and STOP Pain Initiative established under section 2.

SEC. 7. REPORTS.

- (a) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2019 through 2026, the Director of the National Institutes of Health shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a report that includes—
 - (1) the amount obligated or expended in the fiscal year prior to the fiscal year in which the report is being submitted for each program or activity described in this Act (or an amendment made by this Act);

- (2) a description of all such programs or activities carried out using funds provided under this Act (or amendments); and
- (3) a description of how such programs or activities are advancing public health, including the impact on treating pain and addressing opioid misuse in the United States.
- (b) ADDITIONAL REPORTS.—At the request of the Committee on Health, Education, Labor, and Pensions or the Committee on Appropriations of the Senate, or the Committee on Energy and Commerce or the Committee on Appropriations of the House of Representatives, the Director of the National Institutes of Health shall provide to the relevant committee an update in the form of testimony and additional reports concerning the allocation of funding under this Act (or the amendments made by this Act) or the description of the programs and activities carried out with such funding.